

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0010; FRL-9391-9]

SUPPLEMENTARY INFORMATION).

Forchlorfenuron; Temporary Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes temporary tolerances for residues of forchlorfenuron in or on multiple commodities which are identified and discussed later in this document. KIM-C1, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) for uses associated with an experimental use permit. The tolerances expire on December 31, 2015.

DATES: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings must be received on or before [insert date 60 days after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0010, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the

telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Marcel Howard, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6784; email address: howard.marcel@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).
- B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0010 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [insert date 60 days after date of publication in the **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0010, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),
 (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerances

http://www.epa.gov/dockets/contacts.htm.

In the **Federal Register** of February 15, 2013 (78 FR 11126) (FRL-9378-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8055) by KIM-C1, LLC, 2547 West Shaw Avenue, Suite 116, Fresno, CA 93711. The petition requested that 40 CFR 180.569 be amended by establishing temporary tolerances for residues of the plant growth regulator forchlorfenuron, (N-(2-chloro-4-pyridinyl)-N'-phenylurea), in or on almond; cherry, sweet; fig; pear; pistachio; and plum, prune, fresh at 0.01 parts per million (ppm) and almond, hulls at 0.15 ppm. That document referenced a summary of the petition prepared by KIM-C1, LLC, the permittee, which is available to the public in the docket, http://www.regulations.gov. A comment was received on the notice of filing. EPA's response to that comment is discussed in Unit IV.C. These tolerances expire on December 31, 2015.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for forchlorfenuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with forchlorfenuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Forchlofenuron is not acutely toxic via the oral, dermal, and inhalation routes.

Dose-related effects noted in the dog following subchronic and chronic exposure were generally limited to decreased body weight and body-weight gain. In the rat, the only organ that appeared to be affected was the kidney, which showed suppurative

inflammation, suppurative pyelonephritis, non-suppurative interstitial nephritis, and cortical cysts following chronic exposure. Developmental toxicity (decreased fetal body weight and increased pup mortality) was observed in the rat only at a maternally-toxic dose. The developmental toxicity studies in rats and rabbits, as well as the reproductive toxicity study in rats, did not demonstrate any increased pre- or postnatal sensitivity. There was no evidence of neurotoxicity in any of the submitted studies. Forchlorfenuron is classified as not likely to be a human carcinogen and there is no concern for mutagenicity. There was no evidence of endocrine disruption in the forchlorfenuron database.

Specific information on the studies received and the nature of the toxic effects caused by forchlorfenuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in the document titled Forchlorfenuron: Human Health Risk Assessment for Proposed Uses on the Bushberry Subgroup 13B and to Support a Requested Experimental Use Permit on Almonds, Sweet Cherries, Figs, Pears, Pistachios, and Plums/Prunes in docket ID number EPA-HQ-OPP-2007-1065.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which

no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

http://www.epa.gov/pesticides/factsheets/riskassess.htm.

A summary of the toxicological endpoints for forchlorfenuron used for human risk assessment is discussed in Unit II. of the final rule published in the **Federal Register** of August 15, 2008 (73 FR 47843) (FRL-8375-4).

C. Exposure Assessment

- 1. Dietary exposure from food and feed uses. In evaluating dietary exposure to forchlorfenuron, EPA considered exposure from the petitioned-for tolerances as well as all existing forchlorfenuron tolerances in 40 CFR 180.569. EPA assessed dietary exposures from forchlorfenuron in food as follows:
- i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for forchlorfenuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

- ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100% crop treated. Dietary Exposure Evaluation Model (DEEM version 7.81) default processing factors were used for apple juice, dried apples, dried pears, prune juice, cranberry juice, and grape juice. A processing factor was not used for raisins because a separate tolerance (resulting from an empirical processing study) has been established for this commodity. Additionally, the default processing factor was not used for prunes (dried plums) since data indicated that residues in prunes would not exceed the recommended plum tolerance.
- iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that forchlorfenuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for forchlorfenuron. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for forchlorfenuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of forchlorfenuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm.

The conclusions of the Agency in the 2008 human health risk assessment remain

unchanged with respect to dietary exposure and risks. The Agency has verified that the previous estimated drinking water concentrations are also appropriate for use with this experimental use permit (EUP) request.

Forchlorfenuron is persistent and moderately mobile in soils. Forchlorfenuron is also a substituted urea plant growth regulator that is essentially stable to all routes of dissipation except sensitized photodegradation in water. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of forchlorfenuron from the proposed uses on almonds, sweet cherries, figs, pears, plums, and pistachios under the EUP will not exceed the EECs from the grape and kiwi uses previously assessed by the Agency in the document titled Drinking Water Assessment for Forchlorfenuron for Grape and Kiwi Uses. Therefore, the Agency has incorporated the drinking water EEC from the grape and kiwi analysis directly into this dietary assessment.

For chronic exposures for non-cancer assessments are estimated to be 0.32 parts per billion (ppb) for surface water and 0.003 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value 0.32 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Forchlorfenuron is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found forchlorfenuron to share a common mechanism of toxicity with any other substances, and forchlorfenuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that forchlorfenuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

D. Safety Factor for Infants and Children

http://www.epa.gov/pesticides/cumulative.

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA

either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

- 2. Prenatal and postnatal sensitivity. The developmental and reproductive toxicity studies showed no evidence of increased sensitivity or susceptibility of young rats or rabbits following prenatal or postnatal exposure to forchlorfenuron.
- 3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:
 - i. The toxicity database for forchlorfenuron is complete.
- ii. There is no indication that forchlorfenuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that forchlorfenuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to forchlorfenuron in drinking water. EPA used similarly conservative assumptions to assess exposure and risks posed by forchlorfenuron. These assessments will not underestimate the exposure and risks posed by forchlorfenuron.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

- 1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, forchlorfenuron is not expected to pose an acute risk.
- 2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to forchlorfenuron from food and water will utilize < 1% of the cPAD. There are no residential uses for forchlorfenuron.
- 3. Short-term risk and intermediate-term risk. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Forchlorfenuron is currently not registered for any use patterns that would result in short-term and intermediate-term residential exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short- or

intermediate-term risk is necessary. EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for forchlorfenuron.

- 4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, forchlorfenuron is not expected to pose a cancer risk to humans.
- 5. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to forchlorfenuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC/UV method (method # CCRL-MTH-029)) is available to enforce tolerances of forchlorfenuron in/on members of the Bushberry Subgroup 13-07B and the commodities that are the subject of the proposed EUP. Residues are determined by HPLC/UV using external standards and residues are confirmed by liquid chromatography (LC) mass spectrometry (MS/MS) analysis. The validated limit of quantitation (LOQ) is 0.01 ppm for fruit and nut crops.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for forchlorfenuron.

C. Response to Comment

One comment was received in response to the notice of receipt of the EUP's application. The commenter objected to the increase of chemical residues and expressed concerns about the effects of chemicals in general on humans and the environment. The Agency understands the commenter's concerns regarding toxic chemicals and their potential effects on humans and the environment. Pursuant to its authority under the FFDCA, and as discussed further in this preamble, EPA conducted a comprehensive assessment of forchlorfenuron. Based on its assessment of the available data, the Agency has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of forchlorfenuron, including those associated with the EUP.

V. Conclusion

Therefore, temporary tolerances are established for residues of forchlorfenuron, (N-(2-chloro-4-pyridinyl)-N'-phenylurea), including its metabolites and degradates in or on almond; cherry, sweet; fig; pear; pistachio; and plum, prune, fresh at 0.01 ppm and in or on almond, hulls at 0.15 ppm. An expiration date of December 31, 2015, is established for these uses, which are associated with the EUP (71049-EUP-5) the Agency issued to KIM-C1, LLC for plant growth regulator forchlorfenuron.

In addition, consistent with EPA's policy for clarifying its tolerance expressions, EPA is revising the tolerance expression for forchlorfenuron to clarify that the tolerance includes metabolites and degradates of forchlorfenuron and that compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of forchlorfenuron, (N-(2-chloro-4-pyridinyl)-N'-phenylurea).

VI. Statutory and Executive Order Reviews

This final rule establishes temporary tolerances under FFDCA section 408(r) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition submitted under FFDCA section 408(d), such as the tolerance in this final rule, do not

require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

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publication of the rule in the Federal Register. This action is not a "major rule" as

defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural

commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 22, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.569, revise paragraphs (a)(1) introductory text and (a)(2) to read as follows:

§ 180.569 Forchlorfenuron; tolerances for residues.

(a) *General*. (1) Tolerances are established for residues of forchlorfenuron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only forchlorfenuron (*N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea).

* * * * *

(2) Temporary tolerances are established for residues of forchlorfenuron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring on forchlorfenuron (*N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea).

Commodity	Parts per million	Expiration/revocation date
Almond	0.01	12/31/15
Almond, hulls	0.15	12/31/15
Cherry, sweet	0.01	12/31/15
Fig	0.01	12/31/15
Pear	0.01	12/31/15
Pistachio	0.01	12/31/15
Plum, prune, fresh	0.01	12/31/15

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